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Office of Regulatory Policy
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5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

The attached application for patent term extension of U.S. Patent No. 6,031,007 was filed on February 17, 2004, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, ORAQIX, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would NOT be eligible for extension of the patent term under 35 U.S.C. § 156. Lidocaine was previously approved for use in many products, including the product with the proprietary name: OCTOCAINE, applicant: Septodont, which was approved prior to January 1, 1982. In addition, the active ingredient Prilocaine was previously approved in combination with lidocaine on February 4, 1998 with the product having the proprietary name EMLA, applicant: ASTRAZENECA, application number: 020962, approval date: Feb 4, 1998, among other products. Since both active ingredients were previously approved for commercial marketing or use, the regulatory review period of ORAQIX does not support an application for patent term extension. See Arnold Partnership v. Dudas, 70 USPQ2d 1311, 362 F3d 1338 (Fed. Cir. 2004).

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Ferriter
Senior Legal Advisor
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